DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

dmb

Display Date 2-1-07
Publication Date 2-2-07
Certifier

New Animal Drugs for Use in Animal Feeds; Lasalocid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by ADM Alliance Nutrition, Inc. The supplemental NADA provides for the use of a lasalocid Type A medicated article containing 20-percent lasalocid activity per pound to make free-choice Type C medicated feeds used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232; e-mail: *eric.dubbin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305–3115, filed a supplement to NADA 138–993 for use of BOVATEC 91 (lasalocid) Type A medicated article to make MoorMan's Cattle Mineral BT, a free-choice mineral Type C medicated feed used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). The supplement provides for the use of a lasalocid Type A medicated article containing 20-percent lasalocid activity per

NADA 138-993

HFR2

pound. The supplemental NADA is approved as of December 22, 2006, and the regulations are amended in 21 CFR 558.311 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA is revising the regulations to correct a cross reference for a similar product. This is being done to improve the accuracy of the regulations.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subject in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

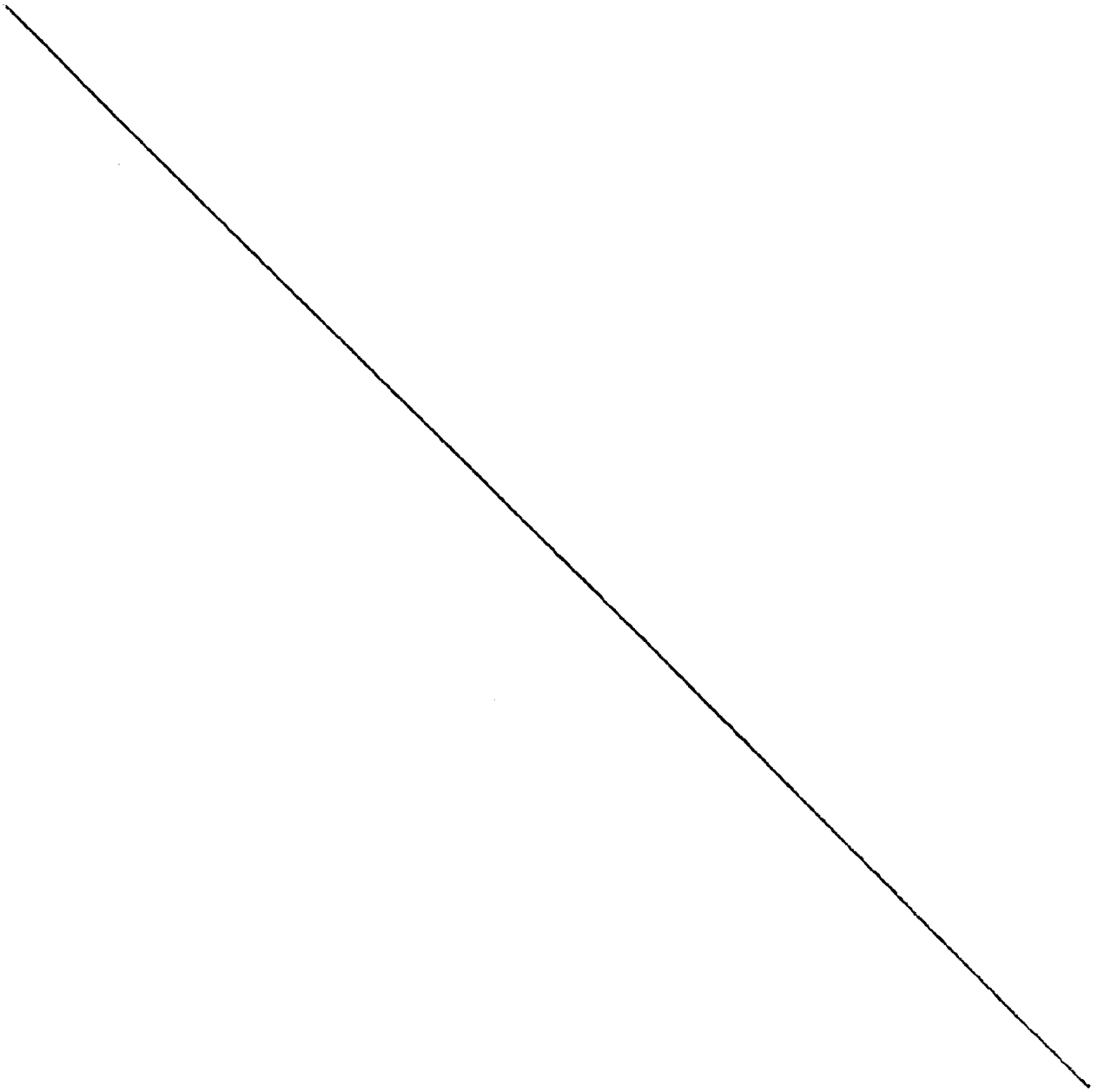
Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.311, remove and reserve paragraph (b)(8), and revise paragraph (b)(5) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *



(5) 15 and 20 percent activity to Nos. 017800 and 021930 for use in free-choice mineral feeds for cattle as in paragraph (e)(1)(xviii) of this section.

* * * * *

Dated: January 24, 2007

January 24, 2007.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 07–????? Filed ??–??–07; 8:45 am]

BILLING CODE 4160–01–S